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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/461,829	12/15/1999	ROBERT-JAN ENZERINK	265280-64723	4338
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WILMER CUTLER PICKERING HALE AND DORR LLP THE WILLARD OFFICE BUILDING 1455 PENNSYLVANIA AVE, NW WASHINGTON, DC 20004			EXAMINER PELLEGRINO, BRIAN E	
			ART UNIT 3738	PAPER NUMBER

DATE MAILED: 02/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/461,829

Applicant(s)

ENZERINK ET AL.

Examiner

Brian E Pellegrino

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 27 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6,35,36,38 and 39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,35,36,38 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1,2,5,6,35 are rejected under 35 U.S.C. 102(b) as being anticipated by Coleman et al. (4469101). Fig. 1 shows a graft material **11** having proximal and distal ends with first and second sets of pre-attached sutures **15**. It can also be seen the device has fixation elements 16 in the form of needles **16**. Coleman et al. disclose the repair device is made of synthetic material, col. 2, lines 67,68. The use of “long strand sutures” is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and reasonably unlimited in how “long” can be interpreted. Thus, the examiner asserts the strands of sutures are long.

Claim 35 is rejected under 35 U.S.C. 102(b) as being anticipated by Dumican et al. (4987665). Fig. 1 shows a replacement ligament **1** having a graft fixation device **4** that lacks bone plugs. Dumican discloses the replacement graft is packaged and sterilized with pre-attached sutures on the surface, col. 11, lines 34-41. Dumican also

discloses the replacement ligament is a non-autologous material, such as polymers, col. 1, lines 65-67 and col. 2.

Claims 1,2,4-6,35,36 are rejected under 35 U.S.C. 102(e) as being anticipated by Roger et al. (6235057). Fig. 2 shows a repair ligament **14** with the proximal and distal ends having first and second set of attached sutures **18,21** securing their respective ends together. Roger et al. disclose that synthetic material can be used for the replacement ligament, col. 2, line 40. Roger et al. teach that bone blocks are not necessary with grafts made from tendons, col. 2, lines 28-31. It is inherent that the artificial or synthetic replacement device is pre-packaged and sterile. The use of "long strand sutures" is terminology of relative degree, which has no basis of comparison. For this reason, it is considered broad and reasonably unlimited in how "long" can be interpreted. Thus, the examiner asserts the strands of sutures are long. Roger additionally discloses the replacement ligament is fixed in the patient with a screw (col. 3, lines 48-65) and inherently would be in the "kit" that the surgeon is using for the ligament repair procedure.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Roger et al. '057 in view of Colleran et al. (5776201). Roger is explained supra. However, Roger does not disclose a plurality of various length ligaments in the kit. Colleran et al. teach (Fig. 4) that kits are packaged with a plurality of prostheses so that the surgeon

Art Unit: 3738

has the proper sized implant that would meet the requirements needed by the patient. It would have been obvious to one of ordinary skill in the art to provide a plurality of different length ligaments as taught by Colleran et al. in the kit of Roger in order to have the proper length necessary for the patient and not have to make modifications during the surgery.

Claims 3,38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Roger et al. '057 in view of McGuire (5562669). Roger is explained supra. However, Roger does not disclose the replacement ligament is an allograft. McGuire teaches that allograft material, such as the semitendinosis tendon can be used as replacement ligaments, col. 5, lines 1,2,8-10, col. 6, lines 32-42. McGuire additionally discloses preserving grafts that are used for future ligament replacement procedures, col. 6, lines 34-36. It is inherent the preserved graft would be sterilized and packaged. It would have been obvious to one of ordinary skill in the art to use packaged allograft tendon material as taught by McGuire in the package or kit of Roger in order to reduce the surgical procedures the patient needs to endure by not having to harvest the replacement graft from the patient.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1 and 35 have been considered but are moot in view of the new ground(s) of rejection.

**Conclusion**

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Pellegrino whose telephone number is (571) 272-4756. The examiner can normally be reached on Monday-Thursday from 6:30am to 4pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached at (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TC 3700, AU 3738  
Primary Examiner  
Brian E. Pellegrino

